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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,386	05/16/2002	Martin Sagasser	DEBE:005US	2267

7590 07/27/2005

Steven L Highlander
Fulbright & Jaworski
Suite 2400
600 Congress Avenue
Austin, TX 78701

EXAMINER	
KALLIS, RUSSELL	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/030,386	SAGASSER ET AL.	
	Examiner	Art Unit	
	Russell Kallis	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-12,23 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22,24-27,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/16/02;10/08/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *attached sequence document*.

5.0.0

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group IV, Claims 13-22, 24-27 and 29-30 and SEQ ID NO: 4 in the reply filed on 5/13/2005 is acknowledged. The traversal is on the ground(s) that SEQ ID NO: 2 should be included with SEQ ID NO: 4 because they are structurally similar. This is not found persuasive because no evidence has been presented to suggest that the two sequences are structurally related.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 are pending. Claims 1-12, 23 and 28 are withdrawn. Claims 13-22, 24-27 and 29-30 are examined.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth: The description of the figures should include the sequence identifiers associated with the sequences in the figures.

> § 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications;
>
> (d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Applicant must amend the claims, specification, and/or drawings to insert sequence identifiers.

Specification

The disclosure is objected to because of the following informalities: On page 12 line31, isoflavon should be spelled isoflavone.

Appropriate correction is required.

Claim Objections

Claim 18 is objected to because of the following informalities: Isoflavon reduktase in line 3 is misspelled as well as cyclohexanon. Appropriate correction is required.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 recites no method steps and thus fails to limit the method of Claim 13.

Claim 21 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The stringent conditions are not defined by the claim and provides no further limitation upon the hybridizing nucleic acid of Claim 20.

Claim 24 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Nothing recited in Claim 24 furhter limits Claim 22. The two products recited in the respective claims are the same.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-18, 20-22, 24-27 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 and sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have an unspecified biological activity as well as nucleic acid sequence that are homologous to an unspecified degree and methods thereby and plants transformed therewith.

Applicants describe SEQ ID NO: 4.

Applicants do not describe nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 or sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have a specific biological activity and methods therewith and plant thereof.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of

cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 or sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have a specific biological activity. Applicants only describe SEQ ID NO: 4. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 or sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have a specific biological activity. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the unspecified biological activity of SEQ ID NO: 4, it remains unclear what features identify nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 or sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have biological activity. Since the genus of sequence that are nucleic acid sequences homologous to SEQ ID NO: 4, fragments and derivatives of SEQ ID NO: 4 or sequences that hybridize to SEQ ID NO: 4 under conditions of unspecified stringency that have a specific biological activity has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Sequences that hybridize with SEQ ID NO: 4 and which are derived or homologous to SEQ ID NO: 4 encompasses naturally occurring allelic variants, mutants of SEQ ID NO: 4, as well as sequences encoding proteins having no known activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of nucleic acids encompassed by the hybridization language or homologous or derivatory language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-18, 21 and 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 13, lines 3-5 and in Claim 29 lines 2-4, the claims recites that the homologous sequence to nucleic acid sequence of SEQ ID NO: 4 or the derivative or fragment of SEQ ID NO: 4 has the biological activity of a polypeptide encoded by SEQ ID NO: 4. However, nucleic acids do not have the biological activity of polypeptides.

The term "modified" in claim 13 is a relative term which renders the claim indefinite. The term "modified" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There is no comparative basis in the claim for any modification, whether the change is an increase or a decrease in total flavonoid content or the

relative distribution of flavonoids or whether the expression of flavonoid would now include parts of the plant not normally found to have flavonoids.

Claim 15 recites the limitation "the formation of flavonoids" in claim 15. There is insufficient antecedent basis for this limitation in the claim.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: there is no recitation of any active method steps in Claim 15 that would inhibit the formation of flavonoids.

The term "stringent conditions" in claim 21 line 2 is a relative term which renders the claim indefinite. The term "stringent conditions" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The term "stringent" could be low or high stringency.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 26 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed inventions encompass untransformed seeds, which are a product of nature and not one of the five classes of patentable subject matter. Claim 26 is drawn to parts such as seeds and progeny of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three

fourths of the progeny having at least a single copy of the transgene and one quarter of the progeny without a copy of the transgene. Since the claim encompasses progeny that lack the transgene, the claim encompasses seeds that are indistinguishable from plants and seeds that would occur in nature. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-18, 20-22, 24-27 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/00501 published 7 January 1999.

The claims are broadly drawn to a method for producing plants with modified flavonoid content comprising stable integration of an unspecified homologous nucleic acid sequence to, an unspecified derivative of, an unspecified fragment of, or a sequence that hybridizes under conditions of unspecified stringency to SEQ ID NO: 4 into the genome of plant cells and the regeneration of a plant.

WO 99/00501 teaches transformation of plants with TTG1 from *Arabidopsis* using the CamV 35S promoter and the TTG1 nucleic acid sequence in antisense orientation, wherein the TTG1 gene would hybridize to SEQ ID NO: 4 under conditions of unspecified stringency, and comprises either an unspecified fragment or unspecified derivative of SEQ ID NO: 4 and

wherein the TTG1 gene is known to modulate anthocyanin (i.e. a flavonoid) levels thus having the biological activity of SEQ ID NO: 4 (see page 3 lines 7-31; page 5 lines 29-32, page 7 lines 5-18, page 38 lines 9-28, page 42 lines 10-17 and page 44 lines 10-16), and thus the reference teaches all the limitations of Claims 13-18, 20-22, 24-27 and 29-30.

Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Shirley B. *et al.* The Plant Journal, 1995, Vol. 5, No. 5; pp. 650-671 in light of Sagasser M *et al.* Genes and Development, 2002 Vol. 16, pp. 138-149 (see page 144 Table 1 and attached sequence document).

Claim 19 is broadly drawn to a nucleic acid segment comprising SEQ ID NO: 4.

Shirley teaches *tt1* is located on chromosome 1 of *Arabidopsis* on page 662 in Figure 2 and Sagasser teaches that *tt1* comprises SEQ ID NO: 4 (i.e. At1g34790); and thus the reference teaches all the limitations of Claim 19.

All Claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
July 22, 2005

RUSSELL P. KALLIS, PH.D.
PATENT EXAMINER

Russell Kallis

Attached Sequence Document

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LOCUS       AF251686               1025 bp    mRNA    linear   PLN 28-JAN-2002
DEFINITION  Arabidopsis thaliana mutant transparent testa 1 protein TT1 (tt1)
            mRNA, tt1-1 allele, complete cds.
ACCESSION   AF251686
VERSION     AF251686.1  GI:18026945
KEYWORDS    .
SOURCE      Arabidopsis thaliana (thale cress)
  ORGANISM  Arabidopsis thaliana
            Eukaryota; Viridiplantae; Streptophyta; Embryophyta; Tracheophyta;
            Spermatophyta; Magnoliophyta; eudicotyledons; core eudicotyledons;
            rosids; eurosids II; Brassicales; Brassicaceae; Arabidopsis.
REFERENCE   1  (bases 1 to 1025)
  AUTHORS   Sagasser,M., Lu,G.H., Hahlbrock,K. and Weisshaar,B.
  TITLE     A. thaliana TRANSPARENT TESTA 1 is involved in seed coat
            development and defines the WIP subfamily of plant zinc finger
            proteins
  JOURNAL   Genes Dev. 16 (1), 138-149 (2002)
   PUBMED   11782451
REFERENCE   2  (bases 1 to 1025)
  AUTHORS   Sagasser,M., Hahlbrock,K. and Weisshaar,B.
  TITLE     Direct Submission
  JOURNAL   Submitted (31-MAR-2000) Abt. Biochemie, MPIZ, Carl-von-Linne-Weg
            10, Koeln D-50829, Germany
FEATURES             Location/Qualifiers
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      121 tcttccctaa cctcaaccaa aactcttgta tcaacaatac cctaattgag cctttaccgc
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      301 tacacatcgg ccttcctggt tttggtaaac caagcaatga tgctaaacag ctgaagaaga
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